

PATENT

Attorney Docket No.: 07189.0014.DVUS02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Joseph S. Podolski	Title:	Methods for Treatment of Erectile Dysfunction
App. No.:	10/700,274	Art Unit:	1616
Conf. No.:	9175	Examiner:	Pryor, Alton Nathaniel
Filing Date:	November 3, 2003		

PETITION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. § 1.705(b)

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby petition the Patent Office under 37 C.F.R. §1.705(b) to reconsider the Patent Term Adjustment (PTA) for the above-referenced application, which is estimated to be 1286 days as indicated on the Notice of Allowance mailed December 7, 2010. The Petition fee of \$200 under 37 C.F.R. 1.705(b)(1) is submitted herewith. This Petition is timely filed as it is being filed no later than payment of the Issue Fee.

No additional fees are believed to be due in connection with the filing of this paper; however, should any further fees be deemed payable (or overpayment creditable), in respect of this communication, the Commissioner is hereby authorized to charge or credit such a fee to Deposit Account No. 08-3038 referencing the above attorney docket number.

Pursuant to 37 C.F.R. 1.705(b)(2), the following statement of facts is provided regarding the basis for why the estimated PTA should be reconsidered. Applicants respectfully submit that the estimated PTA should be increased by **371 days** to a total of 1657 days. The basis for this addition of PTA is due to the administrative delay by the Patent Office in not responding to Applicants' reply under 35 USC 132 within the four month period stipulated under 37 C.F.R. 1.702(a)(2), which is based on 35 U.S.C. 154(b)(1)(A)(ii).

Specifically, Applicants filed a reply under 37 CFR 1.111 on June 28, 2005 and the date for the Patent Office to respond, as guaranteed under 35 USC 154(b)(1)(A)(ii), would have been October 28, 2005. As determined according to the guidelines of 37 C.F.R. 1.703(a)-(a)(2), the administrative delay by the Patent Office beyond the four-month period extended from October 29, 2005 to May 11, 2009, the mailing date of the Patent Office response to Applicants' reply under 35 USC 132.

It was recently decided by the U.S. Court of Appeals for the Federal Circuit in *Wyeth v. Kappos* No. 2009-1120 (Fed. Cir., Jan. 7, 2010) that the manner in which the Patent Office calculates PTAs for patent applications conflicts with the applicable patent statute. Briefly, three different types of administrative delays are considered by the Patent Office when calculating a PTA: type A, B and C delays. While type A delays refer to those set forth under 35 U.S.C. 154(b)(1)(A)(i)-(iv) (e.g. when an Office action is mailed after fourteen months post-filing), a type B delay occurs when a patent is issued after the first three years of an application's pendency. Where both type A and B administrative delays exist in an application, the Patent Office has only considered the longer delay of the two for purposes of calculating a PTA. In other words, the Patent Office has maintained that when both type A and B delays exist in an application, such delay periods necessarily overlap, in which case only the longer of the two periods is assessed to the PTA. However, the Federal Circuit, in *Wyeth*, held that the period of delay for purposes of type A delays runs from the date the Patent Office misses the specified deadline to the date of response to the underlying action and the period of delay for purposes of type B delay runs from the three-year mark after filing until the application issues. With respect to overlap between the type A delay and type B delay, the Federal Circuit held that no overlap occurs unless the violations occur at the same time. In other words, before the three year mark,

no overlap can transpire between type A delay and type B delay because the type B delay has yet to begin or take effect.

The 1286-day PTA for the subject application was estimated by the Patent Office according to its policy to consider only the larger of any A or B delay periods. Of the 1286-day delay, all 1286 days are attributable to type B delay. The 1286 day period represents the time that elapsed from the day after the date that is three years after the filing date (November 4, 2006) to the issue date of the patent as estimated on the Notice of Allowance. The 1286-day PTA incorporates the type B delay but not the type A delay since the latter is shorter in duration. However, the decision in *Wyeth* holds that both A and B delays should be counted when calculating the PTA for an application, at least to the extent that such periods do not directly overlap

In the subject application, the portion of the A delay extending beyond November 3, 2006 directly overlaps with the 1286-day type B delay. In accordance with the *Wyeth* decision, the portion of the type A delay which does not directly overlap with the type B delay (i.e. the 371 day period of time between October 29, 2005 and November 4, 2006) should be added to the PTA. The type A delay does not directly overlap with any type C delay.

As required by 37 C.F.R. 1.705(b)(2)(iii), Applicants indicate that the instant application is subject to terminal disclaimers which disclaim, subject to the stated provisos, the terminal portion of the patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent nos. US 6,696,072 and US 6,482,426.

As required by 37 C.F.R. 1.705(b)(2)(iv)(A), Applicants indicate a 5 day delay in responding to the non-final rejection dated October 26, 2004 and a 100 day delay caused by Applicants' Supplemental Response dated November 19, 2009.

Applicants respectfully submit that the PTA for the subject application should not be reduced by filing this Petition. Pursuant to 37 C.F.R. 1.704(e), the filing of this Petition under 37 C.F.R. 1.705(b) should not be considered as a failure by Applicants to engage in reasonable efforts to conclude processing or examination of the present application. Applicants reserve the right to request reconsideration of any adjustment to the PTA under 37 C.F.R. 1.705(d).

Respectfully submitted,
HOWREY LLP

Dated: March 5, 2010

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